Listing of Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Original) A pharmaceutical carrier or excipient system useful for preparing a pharmaceutical formulation, the carrier or excipient system comprising:

a) a filler and disintegrant component comprising from about 5% to about 82% by weight of the pharmaceutical formulation, of which from about 4% to about 40% by weight of the total formulation comprises one or more pharmaceutically acceptable disintegrants;

b) optionally, a wetting agent comprising from about 0.2 to about 5% of the pharmaceutical formulation;

c) a lubricant comprising from about 0.2% to about 10% of the pharmaceutical formulation; and

d) optionally, a glidant comprising from about 0.1% to about 10% of the pharmaceutical formulation.

2. (Original) The pharmaceutical carrier or excipient system of Claim 1 further comprising from about 0.5% to about 15% by weight of an antioxidant.

3. (Original) The pharmaceutical carrier or excipient system of Claim 2 wherein the antioxidant is selected from ascorbic acid, sodium ascorbate, ascorbyl palmitate, or mixtures thereof.

4. (Original) A pharmaceutical composition comprising a pharmaceutically effective amount of an active pharmacological agent and carrier or excipient system, the carrier or excipient system comprising:

a) a filler and disintegrant component comprising from about 5% to about 82% by weight of the pharmaceutical formulation, of which from about 4% to about 40% by weight of the total formulation comprises one or more pharmaceutically acceptable disintegrants;

b) optionally, a wetting agent comprising from about 0.2 to about 5% of the pharmaceutical formulation;

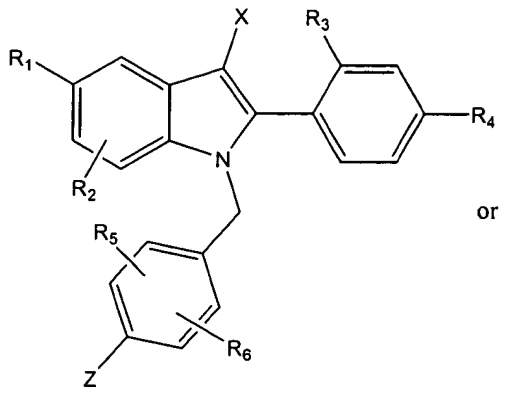
c) a lubricant comprising from about 0.2% to about 10% of the pharmaceutical formulation; and

d) optionally, a glidant comprising from about 0.1% to about 10% of the pharmaceutical formulation.

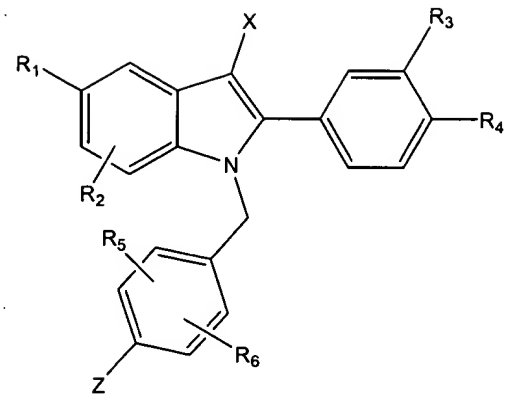
5. (Original) The pharmaceutical carrier or excipient system of Claim 1 further comprising from about 0.5% to about 15% by weight of an antioxidant.

6. (Original) The pharmaceutical carrier or excipient system of Claim 2 wherein the antioxidant is selected from ascorbic acid, sodium ascorbate, ascorbyl palmitate, or mixtures thereof.

7. (Original) A pharmaceutical composition of Claim 4 wherein the pharmacologically active agent is a compound of the formulae I or II:

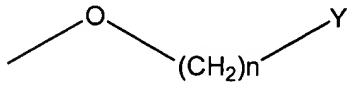


or



I II

wherein Z is a moiety selected from the group of:



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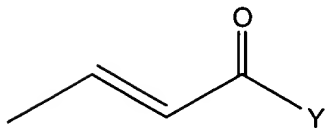

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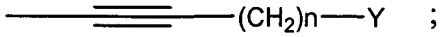
or 

;

wherein:

R_1 is selected from H, OH or the C_1-C_{12} esters or C_1-C_{12} alkyl ethers thereof, benzyloxy, or halogen; or C_1-C_4 halogenated ethers;

R_2, R_3, R_5 and R_6 are independently selected from H, OH or the C_1-C_{12} esters or C_1-C_{12} alkyl ethers thereof, halogens, or C_1-C_4 halogenated ethers, cyano, C_1-C_6 alkyl, or trifluoromethyl, with the proviso that, when R_1 is H, R_2 is not OH;

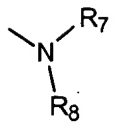
R_4 is selected from H, OH or the C_1-C_{12} esters or C_1-C_{12} alkyl ethers thereof, halogens, or C_1-C_4 halogenated ethers, benzyloxy, cyano, C_1-C_6 alkyl, or trifluoromethyl;

X is selected from H, C_1-C_6 alkyl, cyano, nitro, trifluoromethyl, halogen;

n is 1, 2 or 3;

Y is selected from:

a) the moiety:



wherein R_7 and R_8 are independently selected from the group of H, C_1-C_6 alkyl, or phenyl optionally substituted by CN, C_1-C_6 alkyl, C_1-C_6 alkoxy, halogen, -OH, $-CF_3$, or $-OCF_3$;

b) a five-membered saturated, unsaturated or partially unsaturated heterocycle containing up to two heteroatoms selected from the group consisting of -O-, -NH-, -N(C_1C_4 alkyl)-, -N=, and $-S(O)_m-$, wherein m is an integer of from 0-2, optionally substituted with 1-3 substituents independently selected from the group consisting of hydrogen, hydroxyl, halo, C_1-C_4 alkyl, trihalomethyl, C_1-C_4 alkoxy, trihalomethoxy, C_1-C_4 acyloxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, hydroxy (C_1-C_4)alkyl, $-CO_2H-$, -CN-, $-CONHR_1-$, $-NH_2-$, C_1-C_4 alkylamino, di(C_1-C_4)alkylamino, $-NHSO_2R_1-$, $-NHCOR_1-$, $-NO_2$, and phenyl optionally substituted with from one to three (C_1-C_4)alkyl groups;

c) a six-membered saturated, unsaturated or partially unsaturated heterocycle containing up to two heteroatoms selected from the group consisting of -O-, -NH-, -N(C_1C_4 alkyl)-, -N=, and $-S(O)_m-$, wherein m is an integer of from 0-2, optionally substituted with 1-3 substituents independently selected from the group consisting of hydrogen, hydroxyl, halo, C_1-C_4 alkyl, trihalomethyl, C_1-C_4 alkoxy, trihalomethoxy, C_1-C_4 acyloxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, hydroxy (C_1-C_4)alkyl, $-CO_2H-$, -CN-, $-CONHR_1-$, $-NH_2-$, C_1-C_4 alkylamino, di(C_1-C_4)alkylamino, $-NHSO_2R_1-$, $-NHCOR_1-$, $-NO_2$, and phenyl optionally substituted with from one to three (C_1-C_4)alkyl groups;

d) a seven-membered saturated, unsaturated or partially unsaturated heterocycle containing up to two heteroatoms selected from the group consisting of -O-, -NH-, -N(C_1C_4 alkyl)-, -N=, and -$S(O)_m$-, wherein m is an integer of from 0-2, optionally substituted with 1-3 substituents independently selected from the group consisting of hydrogen, hydroxyl, halo, C_1-C_4 alkyl, trihalomethyl, C_1-C_4 alkoxy, trihalomethoxy, C_1-C_4 acyloxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, hydroxy (C_1-C_4)alkyl, -CO_2H-, -CN-, -$CONHR_1$-, -NH_2-, C_1-C_4 alkylamino, di(C_1-C_4)alkylamino, -$NHSO_2R_1$-, -$NHCOR_1$-, -NO_2, and phenyl optionally substituted with from one to three (C_1-C_4)alkyl groups; or

e) a bicyclic heterocycle containing from 6-12 carbon atoms either bridged or fused and containing up to two heteroatoms selected from the group consisting of -O-, -NH-, -N(C_1C_4 alkyl)-, and -$S(O)_m$-, wherein m is an integer of from 0-2, optionally substituted with 1-3 substituents independently selected from the group consisting of hydrogen, hydroxyl, halo, C_1-C_4 alkyl, trihalomethyl, C_1-C_4 alkoxy, trihalomethoxy, C_1-C_4 acyloxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, hydroxy (C_1-C_4)alkyl, -CO_2H-, -CN-, -$CONHR_1$-, -NH_2-, C_1-C_4 alkylamino, di(C_1-C_4)alkylamino, -$NHSO_2R_1$-, -$NHCOR_1$-, -NO_2, and phenyl optionally substituted with from one to three (C_1-C_4)alkyl groups;
or a pharmaceutically acceptable salt thereof.

8. (Original) The pharmaceutical composition of Claim 7 wherein in the compound of the formulae I or II:

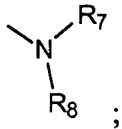
R_1 is selected from H, OH or the C_1-C_{12} esters or alkyl ethers thereof, benzyloxy, or halogen;

R_2, R_3, R_5, and R_6 are independently selected from H, OH or the C_1-C_{12} esters or alkyl ethers thereof, halogen, cyano, C_1-C_6 alkyl, or trihalomethyl; with the proviso that, when R_1 is H, R_2 is not OH;

R_4 is selected from H, OH or the C_1-C_{12} esters or alkyl ethers thereof, benzyloxy, halogen, cyano, C_1-C_6 alkyl, or trihalomethyl;

X is selected from H, C_1-C_6 alkyl, cyano, nitro, trifluoromethyl, halogen;

Y is the moiety



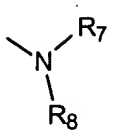
;

R_7 and R_8 are selected independently from H, C_1-C_6 alkyl, or combined by -(CH_2)p-, wherein p is an integer of from 2 to 6, so as to form a ring, the ring being optionally substituted by up to three substituents selected from the group of hydrogen, hydroxyl, halo, C_1-C_4 alkyl, trihalomethyl, C_1-C_4 alkoxy, trihalomethoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, hydroxy (C_1-C_4)alkyl, -CO_2H, -CN, -CONH(C_1-C_4), -NH_3, C_1-C_4 alkylamino, C_1-C_4 dialkylamino, -$NHSO_2$(C_1-C_4), -NHCO(C_1-C_4), and -NO_3;

or a pharmaceutically acceptable salt thereof.

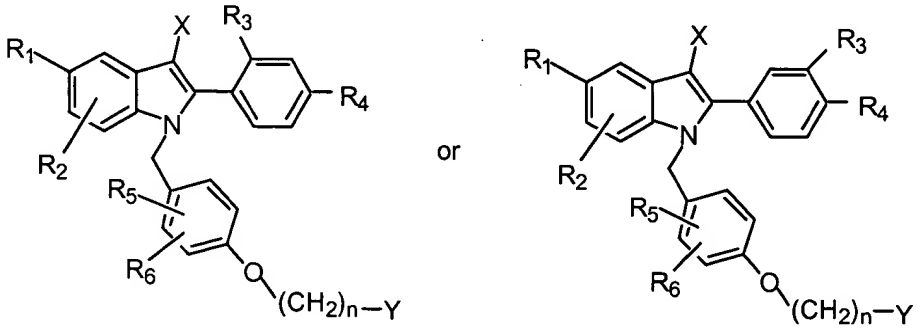
9. (Original) The pharmaceutical formulation of Claim 8 wherein, in the compound of the formulae I or II, the ring formed by a the combination of R_7 and R_8 by -(CH_2)p- is selected from aziridine, azetidine, pyrrolidine, piperidine, hexamethyleneamine or heptamethyleneamine.

10. (Original) The method of Claim 7 utilizing a compound of the formulae I or II, wherein R_1 is OH; R_2 - R_6 are as defined in Claim 1; X is selected from the group of Cl, NO_2, CN, CF_3, or CH_3; and Y is the moiety



and R_7 and R_8 are concatenated together as $-(CH_2)_r-$, wherein r is an integer of from 4 to 6, to form a ring optionally substituted by up to three substituents selected from the group of hydrogen, hydroxyl, halo, C_1-C_4 alkyl, trihalomethyl, C_1-C_4 alkoxy, trihalomethoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, hydroxy (C_1-C_4)alkyl, $-CO_2H$, -CN, $-CONH(C_1$-$C_4)$alkyl, $-NH_2$, C_1-C_4 alkylamino, di(C_1-C_4)alkylamino, $-NHSO_2(C_1$-$C_4)$alkyl, $-NHCO(C_1$-$C_4)$alkyl, and $-NO_2$;
or a pharmaceutically acceptable salt thereof.

11. (Original) A pharmaceutical composition of Claim 4 wherein the active pharmacological agent is a compound of the formulae (III) or (IV):



(III) (IV)

wherein the substituents R_1, R_2, R_3, R_4, R_5, R_6, n, X, and Y are as defined in Claim 7, or a pharmaceutically acceptable salt thereof.

12. (Original) A pharmaceutical composition of Claim 11 wherein:

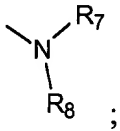
R_1 is selected from H, OH or the C_1-C_{12} esters or alkyl ethers thereof, benzyloxy, or halogen;

R_2, R_3, R_5, and R_6 are independently selected from H, OH or the C_1-C_{12} esters or alkyl ethers thereof, halogen, cyano, C_1-C_6 alkyl, or trihalomethyl, preferably trifluoromethyl, with the proviso that, when R_1 is H, R_2 is not OH;

R_4 is selected from H, OH or the C_1-C_{12} esters or alkyl ethers thereof, benzyloxy, halogen, cyano, C_1-C_6 alkyl, or trihalomethyl;

X is selected from H, C_1-C_6 alkyl, cyano, nitro, trifluoromethyl, halogen;

Y is the moiety

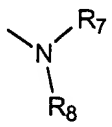


;

R_7 and R_8 are selected independently from H, C_1-C_6 alkyl, or combined by -(CH_2)p-, wherein p is an integer of from 2 to 6, so as to form a ring, the ring being optionally substituted by up to three substituents selected from the group of hydrogen, hydroxyl, halo, C_1-C_4 alkyl, trihalomethyl, C_1-C_4 alkoxy, trihalomethoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, hydroxy (C_1-C_4)alkyl, -CO_2H, -CN, -CONH(C_1-C_4), -NH_3, C_1-C_4 alkylamino, C_1-C_4 dialkylamino, -$NHSO_2$(C_1-C_4), -NHCO(C_1-C_4), and -NO_3;

or a pharmaceutically acceptable salt thereof.

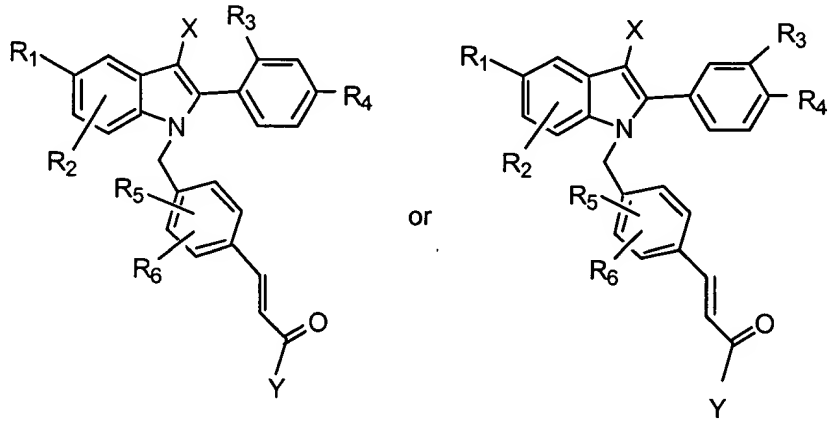
13. (Original) A pharmaceutical composition of Claim 11 wherein R_1 is OH; R_2 - R_6 are as defined above; X is selected from the group of Cl, NO_2, CN, CF_3, or CH_3; and Y is the moiety



and R_7 and R_8 are concatenated together as $-(CH_2)_r-$, wherein r is an integer of from 4 to 6, to form a ring optionally substituted by up to three substituents selected from the group of hydrogen, hydroxyl, halo, C_1-C_4 alkyl, trihalomethyl, C_1-C_4 alkoxy, trihalomethoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, hydroxy (C_1-C_4)alkyl, $-CO_2H$, -CN, $-CONH(C_1$-$C_4)$alkyl, $-NH_2$, C_1-C_4 alkylamino, di(C_1-C_4)alkylamino, $-NHSO_2(C_1$-$C_4)$alkyl, $-NHCO(C_1$-$C_4)$alkyl, and $-NO_2$; or a pharmaceutically acceptable salt thereof.

14. (Original) A pharmaceutical composition of Claim 11 wherein R_7 and R_8 are concatenated together as $-(CH_2)p-$, wherein p is an integer of from 2 to 6, preferably 4 to 6, the ring so formed is optionally substituted with 1-3 substituents selected from a group containing C_1-C_3 alkyl, trifluoromethyl, halogen, hydrogen, phenyl, nitro, -CN.

15. (Withdrawn) A pharmaceutical composition of Claim 4 wherein the active pharmacological agent is a compound of the formulae (V) or (VI):



(V) (VI)

wherein the variable substituents including R_1, R_2, R_3, R_4, R_5, R_6, n, X, and Y are as defined in Claim 7, or a pharmaceutically acceptable salt thereof.

16. (Withdrawn) A pharmaceutical composition of Claim 15 wherein:

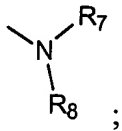
R_1 is selected from H, OH or the C_1-C_{12} esters or alkyl ethers thereof, benzyloxy, or halogen;

R_2, R_3, R_5, and R_6 are independently selected from H, OH or the C_1-C_{12} esters or alkyl ethers thereof, halogen, cyano, C_1-C_6 alkyl, or trihalomethyl, preferably trifluoromethyl, with the proviso that, when R_1 is H, R_2 is not OH;

R_4 is selected from H, OH or the C_1-C_{12} esters or alkyl ethers thereof, benzyloxy, halogen, cyano, C_1-C_6 alkyl, or trihalomethyl;

X is selected from H, C_1-C_6 alkyl, cyano, nitro, trifluoromethyl, halogen;

Y is the moiety

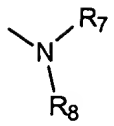


;

R_7 and R_8 are selected independently from H, C_1-C_6 alkyl, or combined by -(CH_2)p-, wherein p is an integer of from 2 to 6, so as to form a ring, the ring being optionally substituted by up to three substituents selected from the group of hydrogen, hydroxyl, halo, C_1-C_4 alkyl, trihalomethyl, C_1-C_4 alkoxy, trihalomethoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, hydroxy (C_1-C_4)alkyl, -CO_2H, -CN, -CONH(C_1-C_4), -NH_3, C_1-C_4 alkylamino, C_1-C_4 dialkylamino, -$NHSO_2$(C_1-C_4), -NHCO(C_1-C_4), and -NO_3;

or a pharmaceutically acceptable salt thereof.

17. (Withdrawn) A pharmaceutical composition of Claim 15 wherein R_1 is OH; R_2 - R_6 are as defined above; X is selected from the group of Cl, NO_2, CN, CF_3, or CH_3; and Y is the moiety

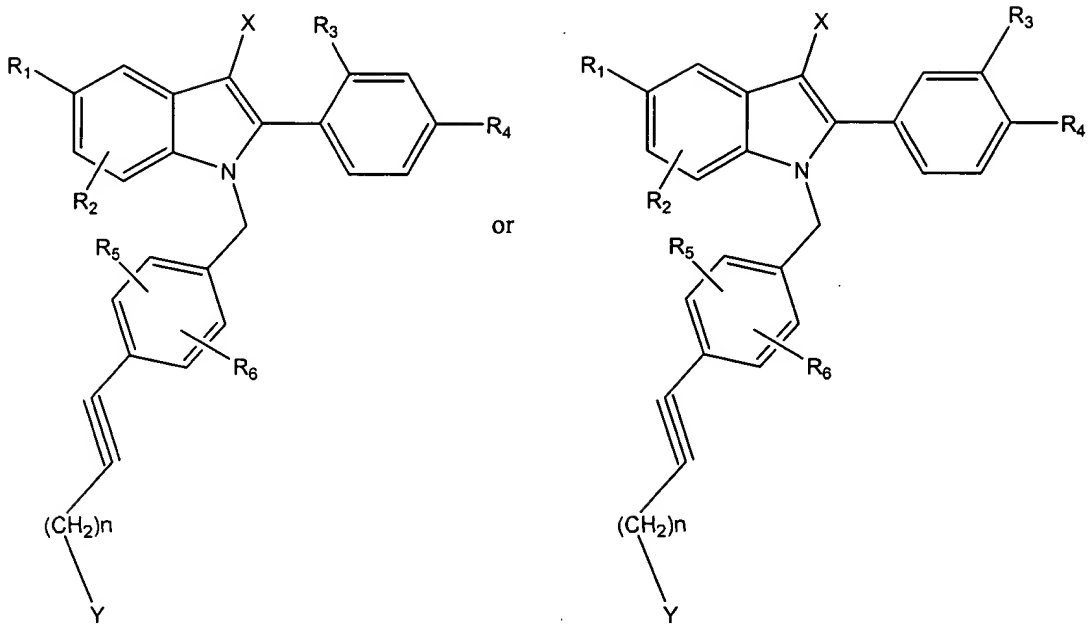


and R_7 and R_8 are concatenated together as $-(CH_2)_r-$, wherein r is an integer of from 4 to 6, to form a ring optionally substituted by up to three substituents selected from the group of hydrogen, hydroxyl, halo, C_1-C_4 alkyl, trihalomethyl, C_1-C_4 alkoxy, trihalomethoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, hydroxy (C_1-C_4)alkyl, $-CO_2H$, -CN, $-CONH(C_1$-$C_4)$alkyl, $-NH_2$, C_1-C_4 alkylamino, di(C_1-C_4)alkylamino, $-NHSO_2(C_1$-$C_4)$alkyl, $-NHCO(C_1$-$C_4)$alkyl, and $-NO_2$; or a pharmaceutically acceptable salt thereof.

18. (Withdrawn) A pharmaceutical composition of Claim 15 wherein R_7 and R_8 are concatenated together as $-(CH_2)p-$, wherein p is an integer of from 2 to 6, preferably 4 to 6, the ring so formed is optionally substituted with 1-3 substituents selected from a group containing C_1-C_3 alkyl, trifluoromethyl, halogen, hydrogen, phenyl, nitro, -CN.

19. (Withdrawn) A pharmaceutical composition of Claim 4 wherein the active pharmacological agent is a compound of the formulae (VII) or (VIII):

(VII) (VIII)



wherein the variable substituents including R_1, R_2, R_3, R_4, R_5, R_6, n, X, and Y are as defined in Claim 7, or a pharmaceutically acceptable salt thereof.

20. (Withdrawn) A pharmaceutical composition of Claim 19 wherein:

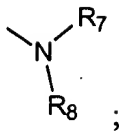
R_1 is selected from H, OH or the C_1-C_{12} esters or alkyl ethers thereof, benzyloxy, or halogen;

R_2, R_3, R_5, and R_6 are independently selected from H, OH or the C_1-C_{12} esters or alkyl ethers thereof, halogen, cyano, C_1-C_6 alkyl, or trihalomethyl, preferably trifluoromethyl, with the proviso that, when R_1 is H, R_2 is not OH;

R_4 is selected from H, OH or the C_1-C_{12} esters or alkyl ethers thereof, benzyloxy, halogen, cyano, C_1-C_6 alkyl, or trihalomethyl;

X is selected from H, C_1-C_6 alkyl, cyano, nitro, trifluoromethyl, halogen;

Y is the moiety

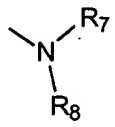


;

R_7 and R_8 are selected independently from H, C_1-C_6 alkyl, or combined by -$(CH_2)p$-, wherein p is an integer of from 2 to 6, so as to form a ring, the ring being optionally substituted by up to three substituents selected from the group of hydrogen, hydroxyl, halo, C_1-C_4 alkyl, trihalomethyl, C_1-C_4 alkoxy, trihalomethoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, hydroxy (C_1-C_4)alkyl, -CO_2H, -CN, -CONH(C_1-C_4), -NH_3, C_1-C_4 alkylamino, C_1-C_4 dialkylamino, -$NHSO_2$(C_1-C_4), -NHCO(C_1-C_4), and -NO_3;

or a pharmaceutically acceptable salt thereof.

21. (Withdrawn) A pharmaceutical composition of Claim 19 wherein R_1 is OH; R_2 - R_6 are as defined above; X is selected from the group of Cl, NO_2, CN, CF_3, or CH_3; and Y is the moiety



and R_7 and R_8 are concatenated together as -$(CH_2)_r$-, wherein r is an integer of from 4 to 6, to form a ring optionally substituted by up to three substituents selected from the group of hydrogen, hydroxyl, halo, C_1-C_4 alkyl, trihalomethyl, C_1-C_4 alkoxy, trihalomethoxy, C_1-C_4 alkylthio, C_1-C_4 alkylsulfinyl, C_1-C_4 alkylsulfonyl, hydroxy (C_1-C_4)alkyl, -CO_2H, -CN, -CONH(C_1-C_4)alkyl, -NH_2, C_1-C_4 alkylamino, di(C_1-C_4)alkylamino, -$NHSO_2$(C_1-C_4)alkyl, -NHCO(C_1-C_4)alkyl, and -NO_2; or a pharmaceutically acceptable salt thereof.

22. (Withdrawn) A pharmaceutical composition of Claim 19 wherein R_7 and R_8 are concatenated together as $-(CH_2)p-$, wherein p is an integer of from 2 to 6, preferably 4 to 6, the ring so formed is optionally substituted with 1-3 substituents selected from a group containing C_1-C_3 alkyl, trifluoromethyl, halogen, hydrogen, phenyl, nitro, -CN.

23. (Original) A pharmaceutical composition of Claim 4 wherein the active pharmacological agent is 1-[4-(2-Azepan-1yl-ethoxy)-benzyl]-2-(4-hydroxy-phenyl)-3-methyl-1H-indol-5-ol or a pharmaceutically acceptable salt thereof.

24. (Withdrawn) A pharmaceutical composition of Claim 4 wherein the active pharmacological agent is 2-(4-Hydroxy-phenyl)-3-methyl-1-(4-(2-piperidin-1-yl-ethoxy)-benzyl]-1H-indol-5-ol or a pharmaceutically acceptable salt thereof.

25. (Original) A pharmaceutical composition of Claim 4 wherein the active pharmacological agent is selected from the group of raloxifene, tamoxifen, droloxifene, arzoxifene or CP 336156, or a pharmaceutically acceptable salt thereof.

26. (Original) A pharmaceutical composition comprising:

a) a pharmaceutically effective amount of 1-[4-(2-Azepan-1yl-ethoxy)-benzyl]-2-(4-hydroxy-phenyl)-3-methyl-1H-indol-5-ol or 2-(4-Hydroxy-phenyl)-3-methyl-1-(4-(2-piperidin-1-yl-ethoxy)-benzyl]-1H-indol-5-ol, or a pharmaceutically acceptable salt thereof;

b) a filler and disintegrant component comprising between about 50% and about 80% of the formulation, with from about 4% to about 40% of the formulation comprising one or more disintegrant agents;

c) a wetting agent comprising between about 0.5% and about 2.5% of the formulation;

d) a lubricant comprising between about 0.2% and about 5% of the formulation; and

e) a glidant comprising between about 0.1% and about 5% of the formulation.

27. (Original) The pharmaceutical composition of Claim 26 further comprising an antioxidant at a concentration of from about 0.5% to about 5% by weight of the composition, the antioxidant being selected from the group of ascorbic acid, sodium ascorbate, ascorbyl palmitate, or mixtures thereof.

28. (Original) The pharmaceutical composition of Claim 26 further being coated with a film coating comprising from about 0.3% to about 8% by weight of the composition.

29. (Original) A pharmaceutical composition comprising:

a) a pharmaceutically effective amount of 1-[4-(2-Azepan-1yl-ethoxy)-benzyl]-2-(4-hydroxy-phenyl)-3-methyl-1H-indol-5-ol or 2-(4-Hydroxy-phenyl)-3-methyl-1-(4-(2-piperidin-1-yl-ethoxy)-benzyl]-1H-indol-5-ol, or a pharmaceutically acceptable salt thereof;

b) a filler and disintegrant component of one or more pharmaceutically acceptable fillers and disintegrants comprising between about 54% and about 87% of the formulation, the disintegrants therein comprising from about 25% to about 35% of the formulation, by weight;

c) a wetting agent comprising between about 0.55% and about 2.7% of the formulation;

d) a lubricant comprising between about 0.2% and about 5.5% of the formulation; and

e) a glidant comprising between about 0.1% and about 5.5% of the formulation.

30. (Original) The pharmaceutical composition of Claim 29 further comprising an antioxidant at a concentration of from about 0.5% to about 5% by weight of the composition, the antioxidant being selected from the group of ascorbic acid, sodium ascorbate, ascorbyl palmitate, or a mixture thereof.

31. (Original) The pharmaceutical composition of Claim 29 further being coated with a film coating comprising from about 0.3% to about 8% by weight of the composition.

32. (Original) A pharmaceutical composition comprising, by weight:

a) from about 2% to about 8% 1-[4-(2-Azepan-1yl-ethoxy)-benzyl]-2-(4-hydroxy-phenyl)-3-methyl-1H-indol-5-ol or 2-(4-Hydroxy-phenyl)-3-methyl-1-(4-(2-piperidin-1-yl-ethoxy)-benzyl]-1H-indol-5-ol, or a pharmaceutically acceptable salt thereof;

b) lactose from about 32% to about 38%;

c) microcrystalline cellulose from about 32% to about 38%;

d) pregelatinized starch from about 12% to about 16%;

e) ascorbic acid from about 1% to about 2%;

f) sodium lauryl sulfate from about 1% to about 2%;

g) sodium starch glycolate from about 4% to about 8%;

h) silicon dioxide from about 0.1% to about 0.2%; and

i) magnesium stearate from about 0.3% to about 0.7%.

33. (Original) A pharmaceutical composition comprising, by weight:

a) from about 0.1% to about 25% 1-[4-(2-Azepan-1yl-ethoxy)-benzyl]-2-(4-hydroxy-phenyl)-3-methyl-1H-indol-5-ol or 2-(4-Hydroxy-phenyl)-3-methyl-1-(4-(2-piperidin-1-yl-ethoxy)-benzyl]-1H-indol-5-ol, or a pharmaceutically acceptable salt thereof;

b) from about 20% to about 80% lactose;

c) from about 4% to about 40% pregelatinized starch;

d) from about 0.2% to about 5% sodium lauryl sulfate;

e) from about 0.5% to about 15% ascorbic acid;

f) from about 0.1% to about 10% silicon dioxide; and

g) from about 0.2% to about 10% magnesium stearate.

34. (Original) A pharmaceutical composition of Claim 33 comprising, by weight:

a) from about 5% to about 18% 1-[4-(2-Azepan-1yl-ethoxy)-benzyl]-2-(4-hydroxy-phenyl)-3-methyl-1H-indol-5-ol or 2-(4-Hydroxy-phenyl)-3-methyl-1-(4-(2-piperidin-1-yl-ethoxy)-benzyl]-1H-indol-5-ol, or a pharmaceutically acceptable salt thereof;

b) from about 47% to about 77% lactose;

c) from about 25% to about 35% pregelatinized starch;

d) from about 1% to about 2% sodium lauryl sulfate;

e) from about 1% to about 3% ascorbic acid;

f) from about 0.1% to about 0.5% silicon dioxide; and

g) from about 0.2% to about 0.5% magnesium stearate.

35. (Previously presented) A pharmaceutical composition comprising:

a) an active pharmacological agent from about 0.1% to about 25% by weight of the pharmaceutical formulation, wherein the active pharmacological agent is 1-[4-(2-Azepan-1yl-ethoxy)-benzyl]-2-(4-hydroxy-phenyl)-3-methyl-1H-indol-5-ol or a pharmaceutically acceptable salt thereof;

b) a filler and disintegrant component comprising from about 20% to about 80% by weight of the pharmaceutical formulation;

c) a disintegrant component comprising from about 4% to about 40% by weight of the pharmaceutical formulation;

d) a wetting agent comprising from about 0.2% to about 5% of the pharmaceutical formulation;

e) an antioxidant comprising from about 0.5% to about 15% of the pharmaceutical formulation;

f) a glidant comprising from about 0.1% to about 10% of the pharmaceutical formulation; and

g) a lubricant comprising from about 0.2% to about 10% of the pharmaceutical formulation.

36. (Previously presented) The pharmaceutical composition of claim 35 wherein the filler and disintegrant component comprises lactose and microcrystalline cellulose.

37. (Previously presented) The pharmaceutical composition of claim 35 wherein the disintegrant component comprises pregelatinized starch.

38. (Previously presented) The pharmaceutical composition of claim 35 wherein the filler and disintegrant component comprises lactose and microcrystalline cellulose; and the disintegrant component comprises pregelatinized starch.

39. (Previously presented) The pharmaceutical composition of claim 38 wherein the antioxidant comprises ascorbic acid.

40. (Previously presented) The pharmaceutical composition of claim 38 wherein the lubricant comprises magnesium stearate.

41. (Previously presented) The pharmaceutical composition of claim 38 wherein the antioxidant comprises ascorbic acid; and the lubricant comprises magnesium stearate.

42. (Previously presented) The pharmaceutical composition of claim 41 wherein the glidant comprises silicon dioxide; and the wetting agent comprises sodium lauryl sulfate.

43. (Previously presented) A pharmaceutical formulation containing a pharmaceutically effective amount of 1-[4-(2-Azepan-1yl-ethoxy)-benzyl]-2-(4-hydroxy-phenyl)-3-methyl-1H-indol-5-ol or a pharmaceutically acceptable salt thereof, and a carrier or excipient system comprising:

a) a filler and disintegrant component comprising between about 50% and about 87% of the formulation, with from about 4% to about 40% of the formulation comprising one or more disintegrant agents;

b) a wetting agent comprising between about 0.5% and about 2.7% of the formulation;

c) a lubricant comprising between about 0.2% and about 5.5% of the formulation; and

d) a glidant comprising between about 0.1% and about 5.5% of the formulation.

44. (Previously presented) The pharmaceutical formulation of claim 43 wherein the filler and disintegrant component comprises lactose and microcrystalline cellulose.

45. (Previously presented) The pharmaceutical composition of claim 43 wherein one of the the disintegrant agents is pregelatinized starch.

46. (Previously presented) The pharmaceutical composition of claim 43 wherein the filler and disintegrant component comprises lactose and microcrystalline cellulose; and one of the disintegrant agents is pregelatinized starch.

47. (Previously presented) A pharmaceutical formulation containing a pharmaceutically effective amount of 1-[4-(2-Azepan-1yl-ethoxy)-benzyl]-2-(4-hydroxy-phenyl)-3-methyl-1H-indol-5-ol or a pharmaceutically acceptable salt thereof, and a carrier or excipient system comprising:

a) a filler and disintegrant component comprising between about 50% and about 87% of the formulation;

b) one or more disintegrant agents comprising from about 4% to about 40% of the formulation;

c) a wetting agent comprising between about 0.5% and about 2.7% of the formulation;

d) a lubricant comprising between about 0.2% and about 5.5% of the formulation; and

e) a glidant comprising between about 0.1% and about 5.5% of the formulation.

48. (Previously presented) The pharmaceutical formulation of claim 47 wherein the filler and disintegrant component comprises lactose and microcrystalline cellulose.

49. (Previously presented) The pharmaceutical composition of claim 47 wherein the disintegrant agents comprise pregelatinized starch and sodium starch glycolate.

50. (Previously presented) The pharmaceutical composition of claim 47 wherein the filler and disintegrant component comprises lactose and microcrystalline cellulose; and the disintegrant agents comprise pregelatinized starch and sodium starch glycolate.

51. (Previously presented) The pharmaceutical composition of claim 50 wherein the wetting agent comprises sodium lauryl sulfate.

52. (Previously presented) The pharmaceutical composition of claim 50 wherein the lubricant comprises magnesium stearate.

53. (Previously presented) The pharmaceutical composition of claim 50 wherein the glidant comprises silicon dioxide.

54. (Previously presented) The pharmaceutical composition of claim 50 wherein the wetting agent comprises sodium lauryl sulfate, the lubricant comprises magnesium stearate, and the glidant comprises silicon dioxide.

55. (Previously presented) The pharmaceutical carrier or excipient system of claim 1 wherein the filler and disintegrant component comprises lactose and microcrystalline cellulose; and the pharmaceutically acceptable disintegrants comprise pregelatinized starch and sodium starch glycolate.

56. (Previously presented) The pharmaceutical carrier or excipient system of claim 2 wherein the filler and disintegrant component comprises lactose and microcrystalline cellulose; and the pharmaceutically acceptable disintegrants comprise pregelatinized starch and sodium starch glycolate.

57. (Previously presented) The pharmaceutical carrier or excipient system of claim 3 wherein the filler and disintegrant component comprises lactose and microcrystalline cellulose; and the pharmaceutically acceptable disintegrants comprise pregelatinized starch and sodium starch glycolate.

58. (Previously presented) The pharmaceutical composition of claim 4 wherein the filler and disintegrant component comprises lactose and microcrystalline

cellulose; and the pharmaceutically acceptable disintegrants comprise pregelatinized starch and sodium starch glycolate.

59. (Previously presented) The pharmaceutical composition of claim 5 wherein the filler and disintegrant component comprises lactose and microcrystalline cellulose; and the pharmaceutically acceptable disintegrants comprise pregelatinized starch and sodium starch glycolate.

60. (Previously presented) The pharmaceutical composition of claim 6 wherein the filler and disintegrant component comprises lactose and microcrystalline cellulose; and the pharmaceutically acceptable disintegrants comprise pregelatinized starch and sodium starch glycolate.

61. (Previously presented) The pharmaceutical carrier or excipient system of claim 1 wherein the filler and disintegrant component consists of lactose and microcrystalline cellulose; and the pharmaceutically acceptable disintegrants are pregelatinized starch and sodium starch glycolate.

62. (Previously presented) The pharmaceutical carrier or excipient system of claim 2 wherein the filler and disintegrant component copsists of lactose and microcrystalline cellulose; and the pharmaceutically acceptable disintegrants are pregelatinized starch and sodium starch glycolate.

63. (Previously presented) The pharmaceutical carrier or excipient system of claim 3 wherein the filler and disintegrant component consists of lactose and microcrystalline cellulose; and the pharmaceutically acceptable disintegrants are pregelatinized starch and sodium starch glycolate.

64. (Previously presented) The pharmaceutical composition of claim 4 wherein the filler and disintegrant component consists of lactose and microcrystalline cellulose; and the pharmaceutically acceptable disintegrants are pregelatinized starch and sodium starch glycolate.

65. (Previously presented) The pharmaceutical composition of claim 5 wherein the filler and disintegrant component consists of lactose and microcrystalline cellulose; and the pharmaceutically acceptable disintegrants are pregelatinized starch and sodium starch glycolate.

66. (Previously presented) The pharmaceutical composition of claim 6 wherein the filler and disintegrant component consists of lactose and microcrystalline cellulose; and the pharmaceutically acceptable disintegrants are pregelatinized starch and sodium starch glycolate.